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EXAMINER	
SHARAREH, SHAHNAM J	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/605,824	KENNEDY ET AL.	
	Examiner	Art Unit	
	Shahnam Sharareh	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/21/2005, 10/29/2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8/24/05,3/26/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's election with traverse of Group II, claims 8-20 and the species of 5-aminolevulinic acid, in the reply filed on Jan 21, 2005 is acknowledged. The traversal is on the ground(s) that no undue burden of search has been established and that the classification is not a proper basis of establishing different field of search. (see Response at page 2). This is not found persuasive because for the purposes of the initial requirement a serious burden on the examiner may be *prima facia* shown if the examiner shows appropriate explanation of separate classification or status in the art (see MPEP §§ 803.01 or 808.02).

Applicant has also argued that merely asserting the claimed invention into different classification is improper grounds for restriction incorrect because such class is directed to diagnostic or test agents. (see Response at page 2). In response Examiner replies that the instant claims 1 and 8 are directed to methods of treating a condition with two different types of compounds, precursors of protoporphyrin IX (claims 1-7) or agents which is not a photosensitizer but induces the synthesis of protoporphyrin IX in vivo (claims 8-20). The scope of the employed compounds are not the same as reasoned in the requirement, thus, *prima facia* evidence of separate classification are adequately provided. . Thus, Applicant's arguments are not persuasive. The requirement is still deemed proper and is therefore made FINAL.

Claims 1-7 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply

filed on Jan 21, 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

2. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

> The second application (which is called a continuing application) must be an application for a patent for an invention which is also disclosed in the first application (the parent or provisional application); the disclosure of the invention in the parent application and in the continuing application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. *See In re Albrecht*, 168 USPQ 293 (CCPA 1971).

In the instant case, the invention as a whole (ie, including limitations set forth in dependent claims) is fully described in Application SN 09/293,835 filed on April 19, 1999, which is divisional to this application.

However, all the other grandparent applications do not sufficiently disclose methods of treating non-malignant lesions of esophagus in a human patient comprising administering to a patient having a non-malignant lesion of esophagus an agent which is not a photosensitizer but induces the synthesis of protoprophyrin IX in vivo and then exposing the site to wavelengths of about 600-700 nanometer to the extent sufficient to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Although some of the dependent claims may have support to earlier filed priority applications, the invention as a whole (ie, including limitations set forth in dependent claims) is fully supported by priority application 09/293,835, filed on April 19, 1999, and acknowledgment is made of applicant's claim for priority under 35 U.S.C. 120. Thus, the

effective priority date used for the examination of the instant application is April 19, 1999.

Applicant is informed that the requirement under 35 USC §112, first paragraph, for "written description of the invention" is separate and distinct from the requirement for enablement. The purpose of the "written description" requirement is broader than to merely explain how to "make and use" or simply disclose an element of a claimed invention; rather, the applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. MPEP 2163.05 (I). Although one might not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed. In re Gosteli, 872 F.2d 1008, 1012,10 USPQ2d 1614, 1618 (Fed. Cir. 1989), MEPE 2163.02. Accordingly, the test for sufficiency of support in a parent application is whether the disclosure of the application relied upon, "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Therefore in the instant case, the possession of the invention as a whole is assessed based on the combined features of the claimed method which includes treating non-malignant lesions of esophagus in a patient by administering compositions that are not photosensitizers, and irradiating the lesion with lights with wavelengths of about 700 nm.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 8-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treating hyperproliferative skin disease or malignant conditions with 5-ALA and exposing the patients to wavelengths of about 350-640 nm, does not reasonably provide enablement for methods of treating non-malignant lesions of esophagus in human patients using any agent that is not a photosensitizer but induces the synthesis of protoporphyrin IX in vivo and then exposing these lesions of esophagus to a wave length of light within the photoactivating spectrum of protoporphyrin IX. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are

weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention

The invention is directed to methods of treating any non-malignant lesion of esophagus with of any agent that is not a photosensitizer but can induce the synthesis of protoporphyrin IX in vivo.

(2) The state of the prior art

The state of art in treating in vivo lesions of human with photodynamic therapy concerns using photosensitizers and 5-ALA in malignant lesions, because such lesions tend to use up photosensitizers and 5-ALA at a much faster rate.

Further, the scope of the term "all agents which are not photosensitzers but induce the synthesis of protoporphyrin IX in vivo" is not clear and specification fails to clearly describe such genus of compounds. In fact, the knowledge about the safety of all agents that are not photosensitizer but induce the synthesis of protoporphyrin IX in vivo is not well known. Moreover, there is no pathway or mechanism described in the art that for identifying such agents. Thus, the in vivo use of all agents that can induce protoporhyrin IX but are not photosensitizers is unpredictable.

(3) The relative skill of those in the art

The art concerns therapeutic approaches utilizing pharmacological and anatomical knowledge. Accordingly, the relative skill of those in the art to practice such invention is viewed to include artisans with a sophisticated understanding of each of the pharmacology, photodynamic and therapeutic science.

(4) The unpredictability of the art

The nature of the applying pharmacological modalities to treat a pathological condition is unpredictable, because there exists substantial agent and inter-patient variability. For example, attention is drawn to Bauer at Pharmacotherapy, A Pathophysiologic Approach, 2nd ed. page 15, 1st para, which states "clinicians should never assume that a serum concentration within the therapeutic range will be safe and effective for every patient."

Further, various scientific groups questioned the selectivity and safety of agents causing photosensitization of celss for photodynamic therapy following systemic administration of such agents. For example, it has been stated that not all photosensitizers accumulate in tissues of interest including for example lesions of esophagus. In fact, various types of porphyrin derivatives have been associated with

slow clearance from the skin which leads to development of cutaneous photosensitivity and severe sunburn. (see Loh et al, J. Photochem. Photobiol.B:Biol 2) (1993), 47-54).

Thus, the nature of the art for the use of all agents that lead to photosensitization of esophageal tissue for treating esophagus lesions by the instant claims is unpredictable.

(5) The breadth of the claims

The breadth of the claim is broad and is not adequately enabled by the specification. The instant claims encompass methods of treating non-malignant lesions of the esophagus with any agent that can induce the synthesis of protoporhyrin IX in vivo. Aside from the fact that the specification fails to define the scope of the term "non-malignant lesions," which can include a scar tissue cause by trauma, an infection or a viral induced lesion, the specification does not provide adequate guidance as to what is the scope and the type of "chemical compounds that are not photosensitizers themselves, but can induce the synthesis of protoporphryin IX in vivo."

In fact, the claims appear to suggest that therapeutic outcome is achieved by inducing the synthesis of protoporhyrin IX in vivo and exposing the lesion of the esophagus to a suitable wavelength. However, the claims do not contain any guideline as to what type of non-malignant lesion of esophagus are candidates for the claimed invention, or how to identify potential useful agents and wavelengths for any potential agent.

There appears to be no common core among the candidate agents within the scope of the invention. Neither is 5-ALA represent the entire genus of the compounds defined as "an agent which is not a photosensitizer but induces the synthesis of protoporphyrin IX in vivo."

Rather, the limitation at issue appears to place a function at the point of novelty for describing the suitable compounds. Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate".

Here, Applicants places a functional language at the point of novelty but fails to meet the requirements set forth under 35 USC 112, first paragraph. The instant claims places the function of an agent "which is not a photosensitizer but induces the synthesis of protoporhyrin IX in vivo," at the point of novelty for purposes of treating non-malignant lesions of the esophagus. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions,

nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468.

Instant claims as constructed provide no guidance as to agents employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, the limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

As it has repeatedly been stressed by the Courts, a method for determining whether a given compound possesses certain desired characteristics and identifies some broad categories of compound that might work, these descriptions, without more precise guidelines, amount to little more that "a starting point, a direction for further research." See *Genetech v. Novo Nordisk A/S,* 108 F.3d 1361,1366, also *Enzo Biochem, Inc. V. Calgene*, Inc, 1888 F.3d 1362, 1374 (Fed. Cir. 1999). Here, the step (a) of the instant claims is exactly a method for determining whether a given compound possesses certain function.

Thus, similar to the cases above, the instant claims appear to place a function at the point of novelty by employing compounds that possesses certain desired characteristic. However, such attempt does not satisfy the statutory requirement set forth under 112 1st para. rather, it simply an invitation to experiment. Thus, practicing the entire scope of the instant claims require undue experimentation.

(6) The amount of direction or guidance presented

The specification discloses in vivo methods of inhibiting cutaneous malignant lesions with 5-ALA. There is no direct teaching employing other compounds for treating non-malginant lesions of esophagus. Rather, the specification relies on hypothetical level of ordinary skill in the art to supply the missing information. Given the broad breadth of the claims the ordinary skill in the art would not have any guidance as what type of compounds should he proceed with.

(7) The presence or absence of working examples

A disclosure does not contain representative examples, which provide reasonable assurance to one skilled in the art that the all claimed agents which is not a photosensitizer but induce the synthesis of protoporphyring IX in vivo can treat all non-malignant lesions of the esophagus in a human patents. The instant specification at most only provides examples of treating cutaneous and hyperproliferative or malignant conditions using 5-ALA. No other examples have been set forth describing the entire scope of the instant claims.

(8) The quantity of experimentation necessary

Considering the above-mentioned factors and the fact that there are significant inter-individual variability and safety issues in using an agent that induces photosensitiation of target cells, the unpredictable nature of art, extensive risk of

adverse events for patients receiving certain agents that lead to photosensitivity; one of ordinary skill in the art would be burdened with undue "experimentation study" to determine all possible compounds useful for treating all sorts of non-malignant lesions of esophagus

Accordingly, claims 8-20 are rejected for undue experimentation.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 8-20 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/605,824. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope and are directed to methods of treating non-malignant lesions of esophagus by administering 5-ALA to a patient and subjecting the patient to light. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant invention, once in possession of the conflicting set of claims.

5. Claims 8-20 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of

copending Application No. 10/170,422. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims overlap in scope and are directed to methods of treating non-malignant lesions of esophagus by administering 5-ALA to a patient and subjecting the patient to light. Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to practice the scope of the instant invention, once in possession of the conflicting set of claims.

These are provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 8-10, 13-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kennedy et al US Patent 5,079,262

Kennedy claims methods of treating non-malignant tissue lesions for digestive track and mucosa by administering to a patient in need thereof an effective amount of 5-ALA and subjecting the lesion to light (see col 7, lines 1-15). Kennedy further teaches that such non-malignant lesions can be the lining of esophagus (see col 4, line 47). The dose of 5-ALA used in Kennedy overlaps with the doses instantly claimed. (see col 5, line 51-col 6, line 53). Thus, Kennedy anticipates methods of treating non-malignant

lesions of the lining of esophagus by administering to the patient sufficient amount of 5-ALA and light.

7. Claims 8-10, 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Bommer US Patent 4,977,177 as evidenced by Stryer's Biochemistry at page 506..

Bommer teaches therapeutic compositions that are useful in phototherapy (abstract). The compounds of Bommer ar tetrapyrrole polyaminocarboxylic acid which are activate at light wavelengths of 620-760 nm. The Tetrapyrroles of Bommer bypass the synthesis of 5-ALA in heme biosynthesis, because as shown by Styer's Biochemistry, they are produced after synthesis of 5-ALA in heme biosynthesis. (See Stryer, figure 21-21 at page 506). Bommer also teaches methods for treating gastric, enteric, esophageal, pharyngeal and pancreatic cancer each of which are established to cause lesions on their respective mucosal region (see col 9, lines 1-20). Examiner also takes the position that when Bommer's compounds are applied systemically and are activated by a wavelength of 620-760 nm, any premalignant regions of the mucosal site at the boarder of the tumor which has not yet become malignant is inherently treated by the agent and exposed to the light with in the meaning of the instant claims. Accordingly, Bommer meets all elements of the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 8-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hinnen et al British Journal of Cancer 1998, 78(5), 679-682 in view of Halling et al US Patent 5,298,502.

Hinnen discloses methods of treating premalignant lesions of esophagus tissues from patints suffering from Barrett's esophagus. Barrett's lesions are premalignant and thus are viewed to fall within the scope of the instant limitation "non-malignant esophagus lesions." (see abstract, pages 680-681). Hinnen uses wavelengths of about 350-650 nm. Hinnen suggests the use of ALA in human patients for selective

photodynamic therapy in Barrett's esophagus (see page 682, last 10 lines). Hinnen only fails to effectively administer ALA to human patients.

Halling teaches the administration of 5-ALA to humans for treating solid tumors of bladder, lungs and even esophagus (see col 1, lines 25-30; xol 8, lines 24-45; col 9, line 10-11, 64-67).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time of invention to employ Hinnen's methods for in vivo application and administer ALA to human patients for treating a non-malignant lesion of esophagus such as Barrett's lesions, because a suggested by Hinnen 5-ALA would be effective for in vivo theapy of Barrett's lesion and as shown by Halling, 5-ALA has in vivo utility.

One of ordinary skill in the art would have had a reasonable expectation of success in employing such method because as suggested by Hinnen himself, the use of 5-ALA would provide successful treatment of Barrett's lesions of esophagus.

Conclusion

No claims were allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh whose telephone number is 571-272-0630. The examiner can normally be reached on 8:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, PhD can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER